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Jean Laible

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application Of

: Group Art Unit: 1615

PANKAJ MODI

: Examiner: T. Ware

Serial No. 09/538,829

: Attorney Docket No. 358594-00010-2

Filed: March 30, 2000

Entitled:
METHOD FOR ADMINISTERING
INSULIN TO THE BUCCAL
REGION

RESPONSE TO EXAMINER'S ANSWER

August 2, 2002

Assistant Commissioner for Patents
BOX AF
Washington, D.C. 20231

Sir:

This is in response to the Examiner's Answer mailed June 5, 2002.

Rejections Under 35 U.S.C. § 102

Claims 26-27 and 37 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Manning et al. (5,770,559). Appellant respectfully submits that Manning does not teach all elements of the claimed invention.

Appellant will not reiterate all previous arguments made here. However, Appellant would like to point out, for the record, that the Examiner's characterization of Appellant's arguments regarding the meaning of an "effective amount", as made in response to the Office Action dated March 13, 2001, are incorrect. The Answer states at page 4 that Appellant's reply set forth that this phrase was not indefinite since the specification provides guidance on how to mix

various amounts of insulin with the micelle formulation. The Examiner now attempts to explain the withdrawal of the §112 rejection of this phrase as due solely to the recognition that the specification provides this guidance.

In fact, Appellant also argued in that response that an effective amount is that amount of insulin necessary to achieve the desired therapeutic result, which is lowering of blood glucose levels. This amount depends on the severity of the illness, the time of day the insulin is administered, and various other factors. Appellant argued that the relationship between administration of insulin and blood glucose has been known for decades. Thus, lacking an explicit statement in the record by the Examiner (other than that now attempted), withdrawal of the §112 rejection was predicated on acceptance of both arguments, that is, one skilled in the art would know how much insulin is an effective amount for therapeutic purposes, and would also know how to mix it in the current formulation.

That being said, the claims at issue do not, as pointed out by the Examiner in the Answer, include the micellar formulation; the Examiner improperly tries to assert that the sole basis for withdrawal of the §112 rejection is because the specification shows how to mix the ingredients, when the claims at issue do not include these ingredients. Appellant respectfully submits that the cited reference does not teach delivery of an effective amount of insulin to the buccal mucosa, and that any amount would not suffice, as asserted by the Examiner; this view is contrary to all that is known about insulin delivery.

As a final point, the Examiner has failed to address the fact that the cited reference does not teach the limitation "while resisting inhalation". Appellant respectfully submits that the cited reference does not teach this limitation, and does not anticipate the claims at issue, Claims 26-27 and 37. Appellant requests withdrawal of this basis of rejection.

Rejections Under 35 U.S.C. § 103

Claims 26-27, 29 and 37 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Manning, '559, and allegedly unpatentable over

Radhakrishnan (5,049, 389). Appellant respectfully submits that the claims are not obvious in view of either reference.

As the Examiner's logic in rejecting Appellant's arguments is repeated in the Answer under this basis of rejection, Appellant reasserts the points made above. These references simply do not teach how to deliver an effective amount of insulin to the buccal mucosa with a metered dose dispenser. Again, the Examiner has failed to address the fact that these references do not teach "resisting inhalation", as recited in the pending claims. Appellant respectfully requests withdrawal of this basis of rejection.

SUMMARY

Appellant respectfully submits that none of the references relied on anticipate or suggest the methods of the present invention. It is respectfully requested, therefore, that the rejection of the pending claims, Claims 26-34 and 36-37, be reversed, and the case remanded to the Examiner for issue of a Notice of Allowance. Such action is respectfully requested at an early date.

Respectfully submitted,



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